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10/563,503	03/02/2006	Patrick Stordeur	DECLE35.005APC	6280

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EXAMINER	
WHISENANT, ETHAN C	

ART UNIT	PAPER NUMBER
1634	

NOTIFICATION DATE	DELIVERY MODE
11/20/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/563,503	STORDEUR ET AL.	
	Examiner	Art Unit	
	Ethan Whisenant, Ph.D.	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-31* is/are allowed.

6)☐ Claim(s) *32-33,37, 39-43, 45-47 and 61* is/are rejected.

7)☒ Claim(s) *32-61* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

NON-FINAL ACTION

1. The applicant's Preliminary Amendment filed 04 JAN 06 has been entered. Following the entry of the Preliminary Amendment, **Claim(s) 1-61** is/are pending.

SEQUENCE RULES

2. This application complies with the sequence rules and the sequences have been entered by the Scientific and Technical Information Center.

35 USC § 112- 2nd Paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH

5. **Claim(s) 32** is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 is indefinite because of the phrase "extracting a pre-determined volume of blood from an individual using said needle or cannula according to Claim 9" on lines 3-4. It is unclear what is intended as Claim 9 is drawn to vessel as claimed in Claim 1 further comprising a fitting suitable for receiving a syringe needle or cannula. For the evaluation of Claim 32 against the prior art the examiner has assumed that the phrase objected to above should read "extracting a pre-determined volume of blood from an individual using the vessel according to Claim 9". Please clarify.

35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

> A person shall be entitled to a patent unless --
>
> **(a)** the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> **(b)** the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> **(e)** the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
> or
> **(e)** the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

CLAIM REJECTIONS UNDER 35 USC § 102

8. **Claim(s) 33, 37, 39** is/are rejected under 35 U.S.C. 102(e) as being anticipated by Helftenbein [US 6,776,959 (2004)].

Claim 33 is drawn to a kit comprising a vessel in which a first substance is present and a container in which an agent is present which agent inhibits cellular degradation and/or gene induction.

Helftenbein teach isolating RNA from a blood sample using a kit (i.e. High Pure RNA Isolation kit, Cat No. 1 828 665) obtained from Boehringer Mannheim which meets all of the structural limitations recited in Claim 33. See the product description obtained from http://www.roche-applied-science.com. Note especially the kit components listed on p.3. As regards the limitations of Claim 33, a vessel in which a first substance is present is equivalent to the container holding the 25 mls of Lysis/binding buffer (i.e. kit component I) while the a container in which an agent is present which agent inhibits cellular degradation and/or gene induction is equivalent to the container holding the 33 mls of Wash buffer I containing guandine HCl (i.e. Kit component IV).

Claim 37 is drawn to a kit according to Claim 33 wherein said first substance is a liquid. This limitation is considered inherent to component I of the kit in that a standard measure for a liquid is recited (i.e. ml, milliliters).

Claim 39 is drawn to a kit according to Claim 33 wherein said vessel comprises one or more openings This limitation is considered inherent to the kit component IV is present in a container capable of holding 33 mls of Wash buffer I to which 20 mls of absolute ethanol is added.. Clearly a solution must be withdrawn from or moved into or the container holding Wash buffer I, in either case the vessel holding Wash buffer I must have at least one opening.

35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a)** A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

CLAIM REJECTIONS UNDER 35 USC § 103

11. **Claim(s) 33, 37, 39-43, 45-47 and 61** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Helftenbein [US 6,776,959 (2004)] in view of the Stratagene Catalog[p.39 (1988)].

Claim 33 is drawn to a kit comprising a vessel in which a first substance is present and a container in which an agent is present which agent inhibits cellular degradation and/or gene induction.

Helftenbein teach isolating RNA from a blood sample using a vacutainer type tube comprising a cell lysis and RNA stabilizing reagent in combination with a kit for isolating RNA (i.e. High Pure RNA Isolation kit, Cat No. 1 828 665 obtained from Boehringer Mannheim). The vacutainer type tube of Helftenbein is the vessel in which

a first substance is present and the container in which an agent is present which agent inhibits cellular degradation and/or gene induction is one or more of the kit components of High Pure RNA Isolation kit. Clearly, Helftenbein does not teach packaging their vacutainer type tube in a kit which also includes the reagents of the High Pure RNA Isolation kit. However, absent an unexpected result it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the High Pure RNA Isolation kit wherein at least one of the vacutainer type tubes of Helftenbein is included. As evidenced by the Stratagene Catalog teaching, it was well known at the time of the invention to place the reagents needed to perform a nucleic acid based assay into a kit format. In addition the Stratagene catalog teaches the advantages of assembling a kit, such as, saving resources and reducing waste. Therefore, absent an unexpected result, it would have been prima facie obvious to the ordinary artisan at the time of the invention to modify the teachings of Helftenbein with the teachings of the Stratagene Catalog wherein the all of the devices/reagents necessary to perform the method of Helftenbein are placed into a kit format. The ordinary artisan would have been motivated to make this modification in order to take advantage of the savings and efficiency afforded by kits.

Claim 37 is drawn to a kit according to Claim 33 wherein said first substance is a liquid. This limitation is considered inherent to component I of the High Pure RNA Isolation kit in that a standard measure for a liquid is recited (i.e. ml, milliliters).

Claim 39 is drawn to a kit according to Claim 33 wherein said vessel comprises one or more openings Helftenbein teach this limitation. See at least figure 1.

Claim 40 is drawn to a kit according to Claim 33 wherein said vessel comprises one or more areas suitable for puncture by a syringe needle. Helftenbein teach this limitation. See at least figure 1.

Claim 41 is drawn to a kit according to Claim 40 wherein said area is a re-sealable septum. Helftenbein teach this limitation. See at least figure 1.

Claim 42 is drawn to a kit according to Claim 33 wherein said vessel comprises one or more fittings suitable for receiving a syringe and transmitting the contents therein to the interior of said vessel. Helftenbein teach this limitation. See at least figure 1.

Claim 43 is drawn to a kit according to Claim 33 wherein said vessel comprises one or more fittings suitable for receiving a hypodermic syringe needle Helftenbein teach this limitation. See at least figure 1.

Claim 45 is drawn to a kit according to Claim 33 wherein said vessel comprises one or more valves which are capable of minimizing the flow from the vessel, minimizing the flow of gas into or from the vessel and/or allowing the flow of liquid biological sample into the vessel . Helftenbein teach this limitation. See at least figure 1.

Claim 46 is drawn to a kit according to Claim 33 wherein said vessel comprises one or more means through which displaced gas may be expelled. Helftenbein teach this limitation. See at least figure 1.

Claim 47 is drawn to a kit according to Claim 33 wherein said vessel Is held under negative pressure. Helftenbein teach this limitation wherein these aurthors teach that the tube utilized is a vacutainer-type tube.

Claim 61 is drawn to a kit according to Claim 33 further comprising one or more oligonucleotides suitable for testing said mRNA(s). Helftenbein teach this limitation. at least Example 7.

REASON FOR ALLOWANCE

12. **Claims 1-31** are allowable over the prior art of record because the prior art considered does not teach or reasonably suggest the vessel recited in Claim 1. In particular, the closest prior art Helftenbein [US 6,776,959(2004)] do not teach or reasonably suggest, either alone or in combination with the other prior art considered, the vessel recited in Claim 1.

CLAIM OBJECTIONS

13. **Claim(s) 32** would appear to be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112 set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

CLAIM OBJECTIONS

14. **Claim(s) 34-36, 38, 44, 48-60** is /are objected to as being dependent upon a rejected base claim, but would appear to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

CONCLUSION

15. **Claim(s) 1-31** is/are allowable while Claim(s) 32-61 is/are rejected and/or objected to for the reason(s) set forth above.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30AM - 5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

The Central Fax number for the USPTO is (571) 273-8300. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

/Ethan Whisenant/
Primary Examiner
Art Unit 1634